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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
11/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketDept@uspatent.com

Office Action Summary	Application No.	Applicant(s)	
	09/852,958	SIRBASKU, DAVID A.	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-38, 41-44, 95-98, 110-114 and 123-146* is/are pending in the application.

4a) Of the above claim(s) *44,96,98,133-135 and 137-146* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-38,42,43,95,97,110, 111, 113, 114,123-132 and 136* is/are rejected.

7)☒ Claim(s) *41 and 112* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 34-38, 41-44, 95-98, 110-114 and 123-146 are all the pending claims for this application.

2. Claims 37, 123, 125, 126 and 128 were amended in the Response of 8/23/10.

3. Claims 44, 96, 98, 133-135 and 137-146 are withdrawn from examination.

4. Claims 34-38, 41-43, 95, 97, 110-114, 123-132 and 136 are the pending claims under examination.

5. This Office Action is final.

Withdrawal of Rejections

Claim Rejections - 35 USC § 112, first paragraph

Biological Deposit

6. The rejection of claims 123, 125, 126, and 128 under 35 U.S.C. § 112, first paragraph, because it is unclear if a cell line for MTW9/PL2, MCF-7K, or H-301 having the exact physical and chemical identity is known and publicly available, or can be reproducibly isolated without undue experimentation is withdrawn.

Applicants have amended the claims in the Response of 8/23/10 to delete reference to the offending cell lines

Claim Rejections - 35 USC § 112, second paragraph

7. The rejection of Claim 37 for the recitation "wherein the nutrient medium further includes non-heat inactivated serum" is withdrawn.

Applicants have amended the claim in the Response of 8/26/10 to clarify the meaning of the

Rejections Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. The rejection of Claims 34, 37, 38, 42, 43, 95, 97, 123-132 and 136 under 35 U.S.C. 103(a) as being unpatentable over Furuya et al (Cancer Research, December 1989, Vol. 49, pp. 6670-6674) in view of Hoffman ('The Biochemistry of Clinical Medicine', 1970, pages 48 and 55) is maintained.

The rejection was set forth in the Office Action of 4/23/10 as follows:

"The interpretation of the claims is of record.
Furuya et al teach that estradiol can neutralize growth inhibition exerted by the ammonium sulfate treated fraction of bovine serum. Furuya et al teach that bovine serum albumin fraction V containing globulin remnants inhibited cell growth, but that globulin-free bovine serum albumin did not inhibit cell growth (abstract). One of skill in

the art would reasonably conclude that serum globulins were potentially the cause of the growth inhibition which estradiol, at sufficiently high concentrations, could overcome. Furuya et al teach that the established human breast cancer cell lines of MCF-7, ZR-75-1 and T47D (page 6670, lines 1-5 under "Introduction"). Furuya et al teach the attempt to study specific growth inhibiting characteristics of a standard, purified amount of a serum constituent as a putative serum-inhibition factor and to determine the genuine effects of exogenous estrogen and/or tamoxifen, including the dual effect of estrogen in the presence of the serum growth inhibitor and a direct mitogenic effect of estrogen, and the inhibition thereof by tamoxifen (page 6670, second column, first full paragraph). Furuya et al teach that low and high doses of tamoxifen exert estrogenic and antiestrogenic effects, respectively, on MCF-7 cells, and that growth inhibition by tamoxifen decreases with increasing concentration of sGF or DCFBS, relative to serum free AIT medium, which when combined with tamoxifen demonstrated a lethal effect on MCF-7 cells (page 6674, fist column). Furuya et al teach that the mechanism of said effect has not yet been elucidated. Furuya et al do not teach growth stimulation by estrogen in the presence of the serum inhibitor which is purified plasma IgA, or purified plasma IgM.

Hoffman et al teach the constituents of serum include IgM, IgG and IgA within the globulin fraction (page 48, figure 4B). Hoffman et al teach that the globulin fraction of serum is ~2.5 g/100 ml of serum and albumin makes up the majority of the remainder of the protein content of serum (page 55, table 10, values for "Normal").

It would have been prima facie obvious to test the inhibitory contribution of various serum globulin proteins, such as IgM, IA or IgG in order t identify the growth inhibitory factor in serum, and the factor responsible for inhibiting the toxic activity of tamoxifen on the human breast cancer cell lines of MCF-7, ZR-75-1 and T47D. One of skill in the art would have been motivated to do so in order to understand the mechanisms and possible in vivo confounding factors effecting the action of drugs such as tamoxifen in vivo. It would have been further obvious to carry out the tests using various combinations of estrogen, tamoxifen and the putative serum inhibitory factors such as IgM, IgG or IgA in multiple samples in order to determine if a statistically significant variation between samples with differing constituents was occurring.

Applicants allegations on pp. 12-14 of the Response of 8/23/10 have been considered and are not found persuasive.

a) Applicants allege Furuya et al. teach away from the use of a nutrient medium including an immunoglobulin; and the purpose of the method taught by Furuya et al. is to look at the effects of estradiol and Tamoxifen on MCF-7 cells in a medium lacking components that can inhibit the growth of the MCF-7 cells.

Response to Arguments

Furuya et al teach the attempt to study specific growth inhibiting characteristics of a standard, purified amount of a serum constituent as a putative serum-inhibition factor and to determine the genuine effects of exogenous estrogen and/or tamoxifen, including the dual effect of estrogen in the presence of the serum growth inhibitor and a direct mitogenic effect of estrogen, and the inhibition thereof by tamoxifen (page 6670, second

column, first full paragraph). Furuya teach in Figure 2a a dose dependent effect of serum borne inhibitors on the presence of endogenous estrogen effects in the proliferation of breast cancer cells: 2 x10 4 cells on day 0 to 4 x 104 cells on day 4 in the presence of 1% DCFBS; and DCFBS above 1% inhibited cell growth in a dose dependent manner. See p. 6672, Col. 1, ¶1 where: "DCFBS…exert a growth-inhibitory effect on MCF-7 cells which can overcome the stimulating effect of 1-10 pM estrogen."

Furuya teach on p. 6673, Col. 3, ¶ 1:

"Different degrees of growth inhibition by BSA-V and globulin-free BSA strongly suggest that a serum factor responsible for growth inhibition exists in the *globulin fraction*, which also includes sex hormone-binding globulin (data not shown)." [*examiner's italics*].

Furuya teach on p. 6673, Col. 3, ¶ 1:

"These interactions should be studied further along with the isolation and characterization of the actual serum growth inhib\- itor. It is still unknown whether this growth inhibitor is the same as the sex hormone-binding globulin or the Mr 53,000 serum inhibitor specific for MCF-7 cells (25)."

Thus contrary to Applicants assertion, Furuya does not teach away from an inhibitor being in the globin fraction or a globin molecule itself but instead provides more than sufficient motivation from an "obvious to try" standpoint, in considering the Ig proteins as the source of endogenous inhibitor. Furuya demonstrates that within a dosage range of the globin fraction that breast cancer cells continue to proliferate in the presence of estrogen.

b) Applicants allege despite Hoffman's teaching the presence of IgA and IgM in globin fractions, the ordinary could not ascertain that the isotypes were inhibitory for cancer cells.

Response to Arguments

Applicants appear to have ignored the tables enclosed with the Hoffman reference on p. 55 where elevated alpha globin levels are correlated with certain cancer types. See especially Table II. Where Furuya provides the motivation to consider globins as having a dose-dependent effect on cancer cell proliferation in vitro and Hoffman shows elevated levels of globin expression for cancers much less the IgA type, the ordinary artisan would have found it "obvious to try" testing the Ig isotypes in the assay method.

c) Applicants allege the date of references suggests that identification of IgA or IgM was not obvious especially in view of Soto.

Response to Arguments

In response to applicant's argument based upon the age of the references, contentions that the reference patents are old or are are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). Here Soto is considered to teach a single example of a kind of inhibitor which does not teach or suggest away from the existence of IgA or IgM also being endogenous globin inhibitors.

The rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. The provisional rejection of Claims 34-38, 42, 43, 95, 110, 111, 113, 114, 123-132 and 136 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 98-109 of copending Application No. 09/852,547 (US 20020006630) is maintained.

The rejection was set forth in the Office Action of 4/23/10 as follows:

"Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '547 render obvious the instant pending claims as follows:
98. A method to detect estrogenic activity of a substance of interest, the method comprising: adding an inhibitory amount of purified IgM to at least two samples of a maintained steroid hormone-responsive cancer cell population in a nutrient medium;
adding an amount of the substance of interest to one of the cell samples to yield a test mixture; designating the cell sample without any added substance of interest as a control mixture; incubating the cell samples for a period of time under cell growth promoting conditions; measuring the cell population in the cell samples after the period of time; and detecting estrogenic activity of the substance of interest from increased cell population doublings in the cell sample treated with the substance of interest compared with the cell sample without any added substance of interest.

99. A method to detect estrogenic activity of a substance of interest, the method comprising: adding an inhibitory amount of purified IgA to at least two samples of a maintained steroid hormone-responsive cancer cell population in a nutrient medium;
adding an amount of the substance of interest to one of the cell samples to yield a test mixture; designating the cell sample without any added substance of interest as a control mixture; incubating the cell samples for a period of time under cell growth promoting conditions; measuring the cell population in the cell samples after the period of time; and detecting estrogenic activity of the substance of interest from increased cell population doublings in the cell sample treated with the substance of interest compared with the cell sample without any added substance of interest.

100. A method to detect estrogenic activity of a substance of interest, the method comprising: adding an inhibitory amount of purified IgM to at least three samples of a maintained steroid hormone-responsive cancer cell population in a nutrient medium;
adding an amount of the substance of interest to one of the cell samples to yield a test mixture; adding an amount of estrogen to one of the cell samples to yield a standard mixture; designating the cell sample without any added substance of interest as a control mixture; incubating the cell samples for a period of time under cell growth promoting conditions; measuring the cell population in the cell samples after the period of time; and detecting estrogenic activity of the substance of interest from a significant increase in cell population doublings in the test mixture and the standard mixture compared with the control mixture.

101. A method to detect estrogenic activity of a substance of interest, the method comprising: adding an inhibitory amount of purified IgA to at least three samples of a maintained steroid hormone-responsive cancer cell population in a nutrient medium;
adding an amount of the substance of interest to one of the cell samples to yield a test mixture; adding an amount of estrogen to one of the cell samples to yield a positive control mixture; designating the cell sample without said substance of interest or estrogen as a negative control mixture; incubating the cell samples for a period of time under cell growth promoting conditions; measuring the cell population in the cell samples after the period of time; and detecting estrogenic activity of the substance of interest from a significant increase in cell population doublings in the test mixture and the standard mixture compared with the control mixture.

102. The method of claim 95 wherein said cells are further selected from the group of cell lines consisting of T47D, MCF-7A, MCF-7K or ZR-75-1.

103. The method of claim 102 wherein said cells are from the T47D cell line.

104. The method of claim 102 wherein said cells are from the ZR-75-1 cell line.

105. The method of claim 102 wherein said cells are further selected from the group consisting of the MCF-7A and MCF-7K cell lines.

106. The method of claim 95 wherein said cells are from the MTW9/PL2 cell line.

107. The method of claim 95 wherein said cells are further selected from the group of cell lines consisting of GH1, GH3 and GH4C 1.

108. The method of claim 107 wherein said cells are from the GH4C 1 cell line.

109. The method of claim 95 wherein said cells are from the H-301 cell line.

The cell lines in the claims of ‘547 are mucosal epithelial cancer cells which read on the instant generic claims.

The specification of ‘547 teaches and defines “a nutrient medium” as follows (MPEP 804 “The specification can be used as a dictionary to learn the meaning of a term in the patent claims. *Toro Co. v. White Consul Indus. Inc.* 199 F.3d. 1295, 1299 (Fed. Cir. 1999)):

“a ferric ion-free, calcium ion-containing, serum-free nutrient medium” [0024];

“steroid hormone depleted serum” [0251];

“serum or plasma was not heat pre-treated, or heat inactivated prior to use” [0216];

“Fibronectin was used with DDM-2MF to promote cell attachment “ [0416];

"The total concentration of transferrin in serum is about 3 mg/mL. Usually, two-thirds of the total is apotransferrin. This amount is more than adequate to chelate Fe (III) in culture medium [0232];

"The preferred thyroid hormone is T.sub.3 (3', 5-triidothyronine (FW 673)), purchased from Sigma as Catalog No. T2752). It is stored desiccated at -20.degree. C. To prepare stocks, 0.5 N NaOH was made by addition of 20 grams of pellets to one liter of water. Then, 67.3 mg of T.sub.3 was added. After dissolving the T.sub.3 with stirring for a few minutes, 25 mL of this stock was diluted up to 250 mL with water, for a final concentration of 0.05 N NaOH. This dilution was sterilized using the 0.2 .mu.m pore diameter filter. At this point, the final stock for storage was 10 .mu.M T.sub.3. Aliquots of this final stock are stored in polystyrene tubes at -20.degree. C. The second thyroid hormone, thyroxin (T.sub.4, sodium salt, pentahydrate FW 888.9), is prepared by the same procedure. For this stock solution, 88.9 mg of T.sub.4 are used. T.sub.4 is purchased from Sigma (Catalog No. T2501). T.sub.4 is used at 10 to 20 times higher concentrations than T.sub.3. Care is taken not to freeze-thaw these preparations. Thyroid hormones have a very broad range of metabolic and growth effects, and many different types of cells require thyroid hormones for growth in serum free culture. [0413]

The variations described next are applicable to the defined media in TABLE 6. Standard phenol red-containing Gibco-BRL D-MEM/F-12 is a preferred basal medium to which the defined media components are added. It contains 0.6 mM to 1.0 M CaCl.sub.2. D-MEM/F-12 can be purchased from Gibco-BRL in the liquid form or can be prepared from the powder formulation using only highly purified water. Alternatively, another suitable basal medium could be used as long as it provides at least the required minimum amounts of necessary nutrients, vitamins and minerals to maintain cell viability of the desired cell line. The calcium concentration range preferred is 0.6 to 10 mM. Calcium stabilizes the inhibitor in cell culture without impairing cell growth. The human breast cancer cell medium, DDM-2MF, was a modification of the original DDM-2 medium (Danielpour D et al. (1988) In Vitro Cell Dev Biol 24, 42-52) and MOM-1 (Ogasawara M and Sirbasku D A (1988) In Vitro Cell Dev Biol 24, 911-920) and contained modified hormone concentrations, deferoxamine (DFX) and fibronectin. Aqueous salt solutions such as tissue culture medium contain hydrolytic polymeric forms of Fe (III) (Spiro T G et al. (1966) J Am Chem Soc 88, 2721-2726). DFX binds this form of Fe (III) with very high affinity (Schubert J (1964) In; Iron Metabolism: The Chemical Basis of Chelation, Springer, Berlin, pp 466-498). If not removed, Fe (III) inhibits hormone-responsive growth in serum-free defined medium (Sirbasku D A et al. (1991) Mol Cell Endocrinol 77, C47-C55; Sato H et al. (1992) Mol Cell Endocrinol 83, 239-251; Eby J E et al. (1993) J Cell Physiol 156, 588-600; Eby J E et al. (1992) Anal Biochem 203, 317-325). The preferred cell growth media for conducting cell growth assays are substantially devoid of unbound Fe (III), i.e., preferably containing less than 1 .mu.M Fe (III), and more preferably containing no more than about 0.15 .mu.M. In preferred growth assay systems described herein, which are substantially devoid of unbound Fe (III), the concentration of free, or active Fe (III) in the medium is less than a cell growth inhibiting amount. Fibronectin was used with DDM-2MF to promote cell attachment. The 35-mm diameter assay dishes were pre-coated by incubation with the designated amount of fibronectin (TABLE 6) for 16 to 48 hours at 37.degree. C. in 2.0 mL of D-MEM/F-12. CAPM human prostatic cancer cell medium was developed to support the growth of tumor cells from this tissue. The composition of CAPM is described in TABLE 6. CAPM also supports the growth of the H301 Syrian hamster kidney tumor cells. DDM-2A, which is a modified form of DDM-2 (Danielpour D et al. (1988) In Vitro Cell Dev Biol 24, 42-52), was preferred for growing MTW9/PL2 cells. PCM-9 defined medium was developed for growing the rat pituitary cell lines. This medium differs from previous PCM formulations (Sirbasku D A et al. (1991) Mol Cell Endocrinol 77, C47-C55; Sato H et al. (1992) Mol Cell Endocrinol 83, 239-251; Eby J E et al. (1993) J Cell Physiol 156, 588-600; Eby J E et al. (1992) Anal Biochem 203, 317-325) in that DFX was substituted for apotransferrin and the triiodothyronine concentration was increased to 1.0 nM. Although DFX and apotransferrin (2 to 50 .mu.g/mL) are the preferred chelators based on their very high specificity and affinities for Fe (III), EDTA at 1 to 10 .mu.M or sodium citrate at 10 to 1000 .mu.M also effectively neutralize the cytotoxic effects of Fe (III) (Eby J E et al. (1993) J Cell Physiol 156, 588-600). Ascorbic acid (vitamin C) also chelates Fe (III), but is used less often because it is unstable in cell culture medium at 37.degree. C. in an oxygen environment in the presence of salts and metals in the medium. Also, at concentrations of 50 to 100 .mu.g/mL, apo-ovotransferrin and apo-lactoferrin also were effective Fe (III) chelators in serum-free defined medium (Eby J E et al. (1993) J Cell Physiol 156, 588-600). Although EGF, aFGF and insulin are the preferred growth factors, several other human recombinant proteins are effective. They have either been purchased or obtained as gifts from Gibco-BRL, Sigma or IMCERA Bioproducts. Insulin-like growth factors I and II (IGF-I and IGF-II) can be used to replace insulin, transforming growth factor .alpha. (TGF.alpha.) replaces EGF, TGF.beta. as an inhibitory supplement, and basic fibroblast growth factor (bFGF) partially replaces aFGF. Insulin can be used to replaced IGF-I and IGF-II. All of these protein growth factors are dissolved under sterile conditions according to manufacturers' instructions and stored as indicated." [0416]; and "estrogens, progesterone and androgens" [0274], which reads on the nutrient medium of the instant claims.

Applicants have not filed a terminal disclaimer or cancelled the offending claims from the 547' application. The rejection is maintained.

Conclusion

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNN BRISTOL whose telephone number is (571)272-6883. The examiner can normally be reached on 8:00-4:30, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/
Primary Examiner, Art Unit 1643